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UNCLAS WARSAW 01611

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APPROVED: EXEC:RRORVIG
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UNCLAS SECTION 01 OF 02 WARSAW 001611

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E.O. 12958: N/A
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SUBJECT: POLAND - PRICE CUTS ON REFUNDABLE DRUGS LIST

¶1. (U) On July 22, 2006 Embassy received a copy of a letter from Polish Health Deputy Minister Boleslaw Piecha to Pawel Zelewski, President of the Innovative Pharmaceutical Companies Association (IPCA). The letter is the Ministry of Health's response to IPCA's concerns with regard to a 13 percent price cut for imported drugs placed on the reimbursement list. According to American pharmaceutical companies affected by this price cut, Piecha's letter does not address any of IPCA's concerns. The letter quotes paragraphs of bills and resolutions justifying the Ministry's action.

¶2. (U) Polish Health Deputy Minister Boleslaw Piecha's letter.

BEGIN TEXT:

Warsaw, 14 JUNE 2006

Mr Pawel Zelewski
President
Management Board
Association of Innovative
Pharmaceutical Companies'
Representatives

In response to a letter dated 29 May 2006 concerning remarks made during public consultations and inter-ministerial agreements to drafts of regulations amending the lists of reimbursed drugs, I should present the following explanations:

I cannot share a position expressed in the said letter as if the drafts of secondary laws concerning the lists of reimbursed drugs sent to public consultations and inter-ministerial agreements were

prepared in violation of the procedure applicable while determining prices for drugs.

Pursuant to Art. 5 of the Prices Act of 5 July 2001 (Dz.U. [Journal of Laws] No. 97, item 1050, as amended), it is the right of the Minister of Health to determine and update official prices of medicinal products and medical devices included in the lists of reimbursed drugs.

Exercising the right of determining official prices he is entitled to, the Minister of Health signed and forwarded for announcement a regulation governing determination of such prices. It is the currently applicable regulation of 20 December 2004 on determining official wholesale and retail prices for medicinal products and medical devices. Pursuant a procedure under the Prices Act this regulation contains prices that have been determined in the manner and pursuant to the principles specified in the Act.

A draft of the regulation that was forwarded for inter-ministerial agreements and public consultations on 17 May 2006 reflects, however, only a change in objective macroeconomic conditions that occurred between Q4. 2003 and Q1. 2006. Due to the fact that official prices determined by the Minister in the currently applicable regulation, though being the same as regards their value expressed in terms of money in relation to the amount of negotiated prices, do not correspond to the actually set value, since they do not include a change in macroeconomic conditions that occurred over the period of those years, therefore it has become necessary to update and equalise them to the level reflecting the price determined pursuant to the principles and the manner specified in the Prices Act.

The change in objective macroeconomic conditions is not a price-determining factor, and the effected adjustment of prices is de facto aimed at maintaining the negotiated price level, and not at changing them. Due to the fact that actions to this end undertaken by the Ministers are not to determine the amount of price, but rather to maintain the price at the negotiated level, I cannot agree with charges made on behalf of the Association of Innovative Pharmaceutical Companies' Representatives. As authorised to determine prices in the manner provided for in applicable regulations, I am also authorised to maintain them at the level negotiated with a pharmaceutical company.

I should point out that maintaining the price at the previously determined level is important not only in view of the provisions under the Prices Act, but it is also of critical importance in relation to proper execution of other applicable acts of law. Pursuant to the provisions of the Act on Health Care Financed from Public Funds of 17 August 2004 (Dz.U. [Journal of Laws], No. 210, item 2135), a drug is reimbursed by the National Health Fund (NFZ) that is obliged to refund the price of a reimbursed drug from health insurance premiums to the extent and manner provided for in the Act. A price the value of which exceeds the negotiated price thus unreasonably increases outflow of financial resources from the NFZ at the expense of other health care services financed by it. In the opinion of the Minister of Health, financial resources that are spent on an unjustified increase of the negotiated price should contribute to positive financial consequences, especially for the patients, through decreasing co-payments for drugs and introduction of new lists of drugs planned in the future, new molecules included.

A price that is determined by the Minister of Health that pursuant to the currently applicable regulations set in Art. 5.4.1 is a price within the meaning of the Prices Act. Pursuant to Art. 3.1 of the said Act whenever there is a reference to a price, it shall be understood to mean the value expressed in monetary units that the buyer is obliged to pay to an entrepreneur for an item of goods or service, inclusive of the value added tax and the excise tax. Due to the fact that the price determined by the Minister concerns an official wholesale and retail price, such price should also include a margin in the amount specified in the Act.

Having explained the above, I should also point out that the terms and manner of agreeing acts of law are governed by regulations, among others, provided in a resolution No. 49 of the Council of Ministers of 19 March 2002 on the rules of work of the Council of

Ministers (M.P. No. 13, item 221). The regulation's draft was subject to two-week long public consultations and inter-ministerial agreements during which individual entities had the right to present their positions concerning presented amendments which was reflected in remarks made by over 100 entities which were thoroughly reviewed and justified reservations were included in the final draft of the regulation.

Boleslaw Piecha
The Minister of Health
Secretary of State

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END TEXT

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